



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,164	04/01/2004	Esther Regina de Rooij	2183-6412US	1592
24247	7590	02/14/2006	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			CHEN, STACY BROWN	
			ART UNIT	PAPER NUMBER
			1648	
DATE MAILED: 02/14/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/817,164	DE ROOIJ ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed December 22, 2005 is acknowledged and entered. Claims 2-27 are pending and under examination. In a series of telephone conversations with Applicant's representative, William Ramey, between 1/18/06 and 1/31/06, allowable subject matter was discussed. However, in the interest of clarifying the record, this action is set forth. This action is made non-final because of the new grounds of rejection below. Any inconvenience is regretted.
2. The objection to claim 27 for lacking proper punctuation is withdrawn in view of Applicant's amendment.
3. The rejection of claim 20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, particularly the term "precious", is withdrawn in view of the amendment to the claim.
4. The rejection of claims 1, 2, 5, 7, 10, 14-18, 20-24 and 26 under 35 U.S.C. 102(b) as being anticipated by Yourno *et al.* (*Journal of Clinical Microbiology*, 1992, 30(11):2887-2892, "Yourno") is withdrawn in view of the amendment of the claims that limits the amount of sample to at least 100 μ l. Yourno does not teach a sample size of at least 100 μ l.
5. The rejection of claims 3, 4, 6, 8, 9, 11-13, 19, 25 and 27 under 35 U.S.C. 103(a) as being unpatentable over Yourno, as applied to claims 1, 2, 5, 7, 10, 14-18, 20-24 and 26 above, and further in view of Gillespie (US 5,482,834) and Higuchi *et al.* (*Bio/Technology*, 1993, 11:1026-1030, "Higuchi"), is withdrawn in view of the amendment of the claims that limits the amount of sample to at least 100 μ l. Yourno, Gillespie and Higuchi all fail to teach a sample size of at least 100 μ l.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The minimum requirements for method steps minimally include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized, and a correlation step describing how the results of the assay allow for the determination.

In the instant claims, a process for detecting and quantifying a nucleic acid of interest is performed by detecting and quantifying a nucleic acid of interest. These method steps do not describe the preamble of the claim beyond reiterating the preamble. The method is actually directed to the preparation of a sample which is subsequently used in a method for detecting and quantifying nucleic acid in that sample. It is suggested that a more appropriate preamble is, "A process for preparing a sample for a method of detecting and quantifying a nucleic acid of interest in the sample." Correction is required to overcome this rejection.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1648

Claims 2-17 and 19-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a method of preparing a sample for a method of detecting and quantifying nucleic acid in the sample. The method of preparation comprises administering 100 μ l of a sample to a solid carrier. This encompasses a large genus of solid carriers, for which Applicant has not adequately demonstrated possession.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of "solid carrier". The specification is clearly directed to the use of filter paper. The specification does not provide adequate description of the non-filter paper carriers that would be useful in the claimed method of absorbing a sample and detecting and quantifying nucleic in said non-filter paper carrier. There is no description of the structure of the non-filter paper carriers, nor of their ability to function in the claimed method. Lacking a structure/function correlation, the claims lack written description for the methods that encompass non-filter paper carriers.

Conclusion

8. Note that the references cited on the attached PTO-892 are from the specification's bibliography. The references are cited on the PTO-892 because Applicant did not cite them on their IDS, however, Applicant requested that they be considered. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Romppanen *et al.* (*Clinical Chemistry*, 1999, 45(11):2022-2025, "Romppanen") teaches a PCR-Oligonucleotide ligation assay from dried blood spots. Romppanen's summary of the literature regarding this subject reveals that dried blood spot specimens on filter blotters are widely used for collection, storage and shipping of blood samples in screening programs. Romppanen discloses that PCR inhibitors can be eliminated from DBS specimens by eluting the spots with methanol, or by extracting the DNA from the disk. In Romppanen's method, DBS specimens are made by dropping 10-20 microliters of fresh or previously frozen blood onto various blotting media, allowing the spots to dry and adding one drop of methanol to the dried spots.

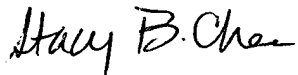
Romppanen's teachings do not anticipate or obviate the instantly claimed invention because the instant method claims require that 100 microliters of sample, or specifically blood, be applied to the blotting medium, filter paper.

No claim is allowed. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions

Art Unit: 1648

on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

A handwritten signature in black ink that reads "Stacy B. Chen". The signature is written in a cursive, flowing style.

Stacy B. Chen
January 31, 2006